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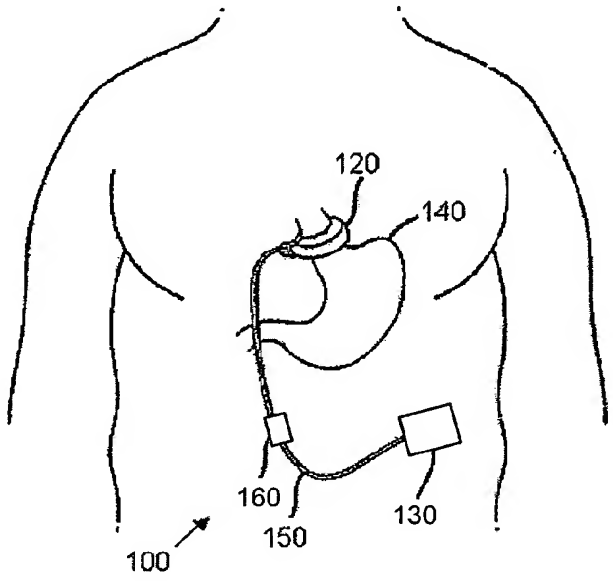
(54) Controlling pressure in adjustable restriction device

(57) Devices are provided for regulating a hydraulic restriction system (120). In general, the devices can allow for non-invasive pressure control using a flow control mechanism (130). The flow control mechanism can be disposed between an implantable restriction device (120) and a fluid source (132) and include an adjustable, variably-sized fluid communication member in fluid communication with the restriction device and the fluid source. The geometry of the fluid communication member can control a rate of fluid flow between the restriction device and the fluid source, thereby also regulating a rate at which a pressure of fluid within the restriction device changes. Alternatively, the fluid flow control mechanism can include a biasing mechanism that can control the rate of fluid flow between the restriction device and the fluid source.

FIG. 1A



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Description

FIELD OF THE INVENTION

[0001] The present invention relates to implantable restriction devices, and in particular to methods and devices for pressure control of fluid in a restriction system.

BACKGROUND OF THE INVENTION

[0002] Obesity is becoming a growing concern, particularly in the United States, as the number of obese people continues to increase and more is learned about the negative health effects of obesity. Morbid obesity, in which a person is 100 pounds or more over ideal body weight, in particular poses significant risks for severe health problems. Accordingly, a great deal of attention is being focused on treating obese patients. One method of treating morbid obesity has been to place a restriction device, such as an elongated band, about the upper portion of the stomach. Gastric bands have typically comprised a fluid-filled elastomeric balloon with fixed endpoints that encircles the stomach just inferior to the esophageal-gastric junction to form a small gastric pouch above the band and a reduced stoma opening in the stomach. When fluid is infused into the balloon, the band expands against the stomach creating a food intake restriction or stoma in the stomach. To decrease this restriction, fluid is removed from the band. The effect of the band is to reduce the available stomach volume and thus the amount of food that can be consumed before becoming "full."

[0003] With each of the above-described food restriction devices, safe, effective treatment requires that the device be regularly monitored and adjusted to vary the degree of restriction applied to the stomach. With banding devices, the gastric pouch above the band will substantially increase in size following the initial implantation. Accordingly, the stoma opening in the stomach must initially be made large enough to enable the patient to receive adequate nutrition while the stomach adapts to the banding device. As the gastric pouch increases in size, the band may be adjusted to vary the stoma size. In addition, it is desirable to vary the stoma size in order to accommodate changes in the patient's body or treatment regime, or in a more urgent case, to relieve an obstruction or severe esophageal dilatation. Traditionally, adjusting a hydraulic gastric band requires a scheduled clinician visit during which a Huber needle and syringe are used to penetrate the patient's skin and add or remove fluid from the balloon via an injection port. More recently, implantable pumps have been developed which enable non-invasive adjustments of the band. An external programmer communicates with the implanted pump using telemetry to control the pump. During a scheduled visit, a physician places a hand-held portion of the programmer near the gastric implant and transmits power and command signals to the implant. The implant in turn adjusts the fluid levels in the band and transmits a response command to the programmer. While such pumps can be effective, they require power to operate, requiring patients to visit physicians for the pumps to properly operate and be maintained.

[0004] Accordingly, there remains a need for methods and devices for regulating a hydraulic restriction system, and in particular for regulating the rate of fluid flow between a restriction device and a fluid source, preferably without the use of power to operate.

SUMMARY OF THE INVENTION

[0005] The present invention generally provides methods and devices for regulating a hydraulic restriction system. In one embodiment, a restriction system for forming a restriction in a patient is provided that includes an implantable restriction device configured to form a restriction in a pathway as a function of a volume of fluid contained in the restriction device. The system also includes an adjustable flow control mechanism in fluid communication with the restriction device and configured to define a rate of fluid flow to and from the restriction device.

[0006] In one embodiment, the adjustable flow control mechanism can have a geometry that defines a rate of fluid flow to and from the restriction device. The flow control mechanism can be adjustable between a plurality of fixed positions such that increasing the a volume of the geometry increases the rate of fluid flow and decreasing a volume of the geometry decreases the rate of fluid flow. The fluid control mechanism's geometry can be adjusted, for example, through linear motion. In some embodiments, the geometry defines a rate of fluid flow between the restriction device and a fluid reservoir included in the system.

[0007] The flow control mechanism can have a variety of configurations. For example, the flow control mechanism can include a flexible tube disposed in a housing and in fluid communication with the restriction device. The geometry of the flexible tube can be adjusted by modifying an amount of fluid within the housing. In some embodiments, the housing is in fluid communication with an implantable port, and the amount of fluid within the housing can be modified through the port. As another example, the flow control mechanism can include a pathway in fluid communication with the restriction device, wherein a geometry of the pathway is configured to be adjusted by adjusting an amount of an obstruction mechanism within the pathway. As yet another example, the flow control mechanism can include a porous membrane.

[0008] In other aspects, the flow control mechanism can include a porous member disposed within a fluid-filled housing. Fluid in the housing can be configured to regulate a rate of movement of the porous member through the housing to thereby regulate the rate of fluid flow to and from the restriction device. In an exemplary embodiment, the porous member is coupled to a fluid source in fluid communication with the restriction device such that movement of the porous member through the

fluid-filled housing is effective to cause fluid to flow between the fluid source and the restriction device. The flow control mechanism can be regulated by regulating a viscosity of fluid in the fluid-filled housing and/or altering a biasing force of a biasing mechanism coupled to the porous member.

[0009] In another embodiment, a restriction system includes an implantable restriction device that can contain a fluid and form a restriction in a pathway corresponding to an amount of fluid in the restriction device. A fluid source can be in fluid communication with the restriction device for receiving fluid from the restriction device to decrease the restriction and for delivering fluid to the restriction device to increase the restriction. The system can further include an adjustable flow control mechanism disposed between the restriction device and the fluid source that can regulate a flow rate of fluid between the fluid source and the restriction device.

[0010] The flow control mechanism can have a variety of configurations. For example, the flow control mechanism can have a diameter that is adjustable between at least two positions to regulate the flow rate of fluid. Increasing the diameter can increase the flow rate of fluid, and decreasing the diameter can decrease the flow rate of fluid. As another example, the flow control mechanism can include a flexible tube disposed in a housing and having a diameter that defines the flow rate of fluid. The diameter of the flexible tube can be adjusted by modifying an amount of fluid within the housing. In some embodiments, the housing can be in fluid communication with an implantable port, and the amount of fluid within the housing can be modified through the port. As still another example, the flow control mechanism can include a porous membrane.

[0011] The fluid source can also have a variety of configurations. For example, the fluid source can include a pressured fluid reservoir, and the flow control mechanism's fixed diameter can define a flow rate of fluid between the pressured fluid reservoir and the restriction device. Fluid can flow at a rate defined by the flow control mechanism's fixed diameter from the restriction device and through the flow control mechanism to the fluid reservoir when a pressure in the restriction device exceeds a pressure in the fluid reservoir. The pressured fluid reservoir can also have a variety of configurations. In some embodiments, the pressured fluid reservoir includes a cavity in fluid communication with the flow control mechanism and a mechanism configured to apply a biasing force to fluid in the cavity.

[0012] In other aspects, a method of forming a restriction in a patient is provided. The method includes implanting a restriction device to form a restriction in a pathway that corresponds to a volume of fluid in the restriction device. The restriction device receives fluid from and delivers fluid to a fluid source at a flow rate defined by a diameter of a flow control mechanism in fluid communication with and disposed between the restriction device and the fluid source. The flow control mechanism's geometry can be adjusted to adjust the flow rate. Increasing the geometry can increase the flow rate, and decreasing the geometry can decrease the flow rate. In some embodiments, the flow control mechanism can include a flexible tube disposed in a fluid cavity, and a geometry of the flexible tube can be adjusted by modifying an amount of fluid within the fluid cavity.

[0013] The following is a non-exhaustive list of embodiments of the invention that may be claimed in this application or in subsequently filed divisional applications:

1. A restriction system for forming a restriction in a patient, comprising:

    an implantable restriction device configured to form a restriction in a pathway as a function of a volume of fluid contained in the restriction device; and
    an adjustable flow control mechanism in fluid communication with the restriction device and configured to define a rate of fluid flow to and from the restriction device.

2. The system of embodiment 1, wherein the adjustable flow control mechanism has an adjustable geometry that defines the rate of fluid flow to and from the restriction device.

3. The system of embodiment 2, wherein the flow control mechanism is configured to be adjustable between a plurality of fixed positions, and wherein increasing a volume of the geometry increases the rate of fluid flow and decreasing a volume of the geometry decreases the rate of fluid flow

4. The system of embodiment 2, wherein the flow control mechanism includes a flexible tube disposed in a housing and in fluid communication with the restriction device, wherein a geometry of the flexible tube is configured to be adjusted by modifying an amount of fluid within the housing to thereby adjust the rate of fluid flow.

5. The system of embodiment 4, wherein the housing is in fluid communication with an implantable port and the amount of fluid within the housing is configured to be modified through the port.

6. The system of embodiment 2, further comprising a fluid reservoir, wherein the geometry defines a rate of fluid flow between the restriction device and the fluid reservoir.

7. The system of embodiment 2, wherein the geometry comprises a diameter.

8. The system of embodiment 2, wherein the geometry of the flow control mechanism is configured to be adjusted through linear motion.

9. The system of embodiment 2, wherein the flow control mechanism includes a pathway in fluid communication with the restriction device, wherein a geometry of the pathway is configured to be adjusted by adjusting an amount of an obstruction mechanism

within the pathway.

10. The system of embodiment 1, wherein the flow control mechanism includes a porous membrane.

11. The system of embodiment 1, wherein the flow control mechanism includes a porous member disposed within a fluid-filled housing, wherein fluid in the housing is configured to regulate a rate of movement of the porous member through the housing to thereby regulate the rate of fluid flow to and from the restriction device.

12. The system of embodiment 11, wherein the porous member is coupled to a fluid source in fluid communication with the restriction device such that movement of the porous member through the fluid-filled housing is effective to cause fluid to flow between the fluid source and the restriction device.

13. A restriction system, comprising:

an implantable restriction device configured to contain a fluid and to form a restriction in a pathway corresponding to an amount of fluid in the restriction device;

a fluid source in fluid communication with the restriction device for receiving fluid from the restriction device to decrease the restriction and for delivering fluid to the restriction device to increase the restriction; and

an adjustable flow control mechanism disposed between the restriction device and the fluid source and configured to regulate a flow rate of fluid between the fluid source and the restriction device.

14. The system of embodiment 13, wherein the flow control mechanism has a diameter that is adjustable between at least two positions to regulate the flow rate of fluid.

15. The system of embodiment 14, wherein increasing the diameter increases the flow rate of fluid, and decreasing the diameter decreases the flow rate of fluid.

16. The system of embodiment 14, further comprising a pressured fluid reservoir, wherein the diameter defines a flow rate of fluid between the pressured fluid reservoir and the restriction device.

17. The system of embodiment **Error! Reference source not found.**, wherein the pressured fluid reservoir includes a cavity in fluid communication with the flow control mechanism and a mechanism configured to apply a biasing force to fluid in the cavity.

18. The system of embodiment **Error! Reference source not found.**, wherein fluid flows at a rate defined by the fixed diameter from the restriction device and through the flow control mechanism to the fluid reservoir when a pressure in the restriction device exceeds a pressure in the fluid reservoir.

19. The system of embodiment 13, wherein the flow control mechanism includes a flexible tube disposed in a housing and having a diameter that defines the flow rate of fluid, wherein the diameter of the flexible tube is configured to be adjusted by modifying an amount of fluid within the housing.

20. The system of embodiment **Error! Reference source not found.**, wherein the housing is in fluid communication with an implantable port and the amount of fluid within the housing is configured to be modified through the port.

21. The system of embodiment 13, wherein the flow control mechanism includes a porous membrane.

22. A method of forming a restriction in a patient, comprising:

implanting a restriction device to form a restriction in a pathway that corresponds to a volume of fluid in the restriction device, and the restriction device receiving fluid from and delivering fluid to a fluid source at a flow rate defined by a geometry of a flow control mechanism in fluid communication with and disposed between the restriction device and the fluid source.

23. The method of embodiment 15, further comprising adjusting the geometry of the flow control mechanism to adjust the flow rate.

24. The method of embodiment **Error! Reference source not found.**, wherein the geometry is increased to adjust the diameter of the flow control mechanism and increase the flow rate.

25. The method of embodiment **Error! Reference source not found.**, wherein the geometry is decreased to adjust the diameter of the flow control mechanism and decrease the flow rate.

26. The method of embodiment **Error! Reference source not found.**, wherein the flow control mechanism includes a flexible tube disposed in a fluid cavity, and wherein adjusting a geometry of the flexible tube comprises modifying an amount of fluid within the fluid cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

[0015] FIG. 1A is a schematic diagram of one embodiment of a food intake restriction system;

[0016] FIG. 1B is a perspective, schematic view of the food intake restriction system of FIG. 1A;

[0017] FIG. 2A is a perspective view of a gastric band of the food intake restriction device of FIG.1A;

[0018] FIG. 2B is a schematic diagram of the gastric band of FIG. 2A applied about the gastro-esophageal junction of a patient;

[0019] FIG. 3A is a schematic diagram of one embodiment of a fluid source that can be used in the food intake restriction system of FIG. 1B;

[0020] FIG. 3B is a schematic diagram of another embodiment of a fluid source that can be used in the food intake restriction system of FIG. 1B;

[0021] FIG. 3C is a schematic diagram of still another embodiment of a fluid source that can be used in the food intake restriction system of FIG. 1B;

[0022] FIG. 3D is a schematic diagram of yet another embodiment of a fluid source that can be used in the food intake restriction system of FIG. 1B;

[0023] FIG. 4 is a perspective view of one embodiment of an injection port housing of the food intake restriction system of FIG. 1B;

[0024] FIG. 5 is a schematic diagram of one embodiment of a flow control mechanism that can be used in the food intake restriction system of FIG. 1A;

[0025] FIG. 6 is a cross-sectional view of a fluid communication member of the flow control mechanism of FIG. 5;

[0026] FIG. 7 is a schematic diagram of the flow control mechanism of FIG. 5 having a fluid communication member with an increased diameter;

[0027] FIG. 8 is a schematic diagram of the flow control mechanism of FIG. 5 having a fluid communication member with a decreased diameter;

[0028] FIG. 9 is a schematic diagram of the flow control mechanism of FIG. 5 having a fluid communication member with a decreased diameter and an increased length;

[0029] FIG. 10 is a schematic diagram of the flow control mechanism of FIG. 5 having a fluid communication member with an increased diameter and a decreased length;

[0030] FIG. 11 is a cross-sectional view of an alternate embodiment of a fluid communication member that can be included in the flow control mechanism of FIG. 5;

[0031] FIG. 12 is a schematic diagram of another embodiment of a flow control mechanism that can be used in the food intake restriction system of FIG. 1A;

[0032] FIG. 13 is a schematic diagram of a variation of the flow control mechanism of FIG. 12;

[0033] FIG. 14 is a schematic diagram of still another embodiment of a flow control mechanism that can be used in the food intake restriction system of FIG. 1A;

[0034] FIG. 15 is an expanded schematic diagram of the flow control mechanism of FIG. 14;

[0035] FIG. 16 is a schematic diagram of a food intake restriction system in use in a dormant stage;

[0036] FIG. 17 is a schematic diagram of the food intake restriction system of FIG. 16 in use in a force stage following the dormant stage of FIG. 16;

[0037] FIG. 18 is a schematic diagram of the food intake restriction system of FIG. 16 in use following the force stage of FIG. 17;

[0038] FIG. 19A is a schematic diagram of another food intake restriction system in use; and

[0039] FIG. 19B is a schematic diagram of an alternate version of the food intake restriction system of FIG. 19A.

DETAILED DESCRIPTION OF THE INVENTION

[0040] Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those skilled in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

[0041] The present invention generally provides methods and devices for regulating a hydraulic restriction system. In general, the methods and devices can allow for non-invasive pressure control using a flow control mechanism disposed between an implantable restriction device and a fluid source. The flow control mechanism can include an adjustable fluid communication member in fluid communication with the restriction device and the fluid source. In certain embodiments, the geometry of the fluid communication member can control a rate of fluid flow between the restriction device and the fluid source, thereby also regulating a rate at which a pressure of fluid within the restriction device changes. Using the flow control mechanism can provide a time-controlled regulation of pressure of fluid in the restriction device because the larger the geometry of the fluid communication member, the faster fluid can flow between the restriction device and the fluid source, while the smaller the geometry of the fluid communication member, the slower fluid can flow between the restriction device and the fluid source. In other words, the flow control mechanism can provide a delay-controlled regulation of fluid pressure in the restriction device that can be configured to respond more quickly (e.g., with a larger geometry) or more slowly (e.g., with a smaller geometry) to at least one parameter of restriction device function or patient physiology that varies as a function of food intake or other patient physiologic condition. In this way, the flow control mechanism can provide a more constant pressure within the restriction device over time. Because the flow control mechanism can prevent fluid from immediately flowing to or from the restriction device, temporary or transitory changes in the restriction device and/or in the patient (e.g., restriction device pressure increases during eating due to the presence of food and peristaltic waves during swallowing) do not necessarily result in a significant increase or decrease of fluid in the restriction device before the temporary or transitory changes decrease or disappear from effect. In other embodiments, a biasing mechanism, such as a fluid-filled housing for limiting movement of an actuator for driving fluid between the fluid source and re-

striction device and/or a spring coupled to the actuator, can control the rate of fluid flow between the restriction device and the fluid source. The use of the flow control mechanism can also mechanically regulate a rate of the pressure change of the restriction device without the use of any electrical components that may need to be powered to operate over extended periods of time.

[0042] While the present invention can be used with a variety of restriction systems known in the art, in an exemplary embodiment the devices and methods are used with a gastric restriction device. While various types of gastric restriction devices are known, including electrical, mechanical, and/or fluid-based devices, for reference purposes the devices and methods disclosed herein are discussed in connection various embodiments of a fluid-based gastric restriction device as disclosed in commonly-owned U.S. Publication No. 2006/0211913 of Dlugos et al. (hereinafter "Dlugos") filed on March 7, 2006 and entitled "Non-Invasive Pressure Measurement In A Fluid Adjustable Restrictive Device," which is hereby incorporated by reference in its entirety. A person skilled in the art will appreciate that the methods and devices disclosed herein are not intended to be limited to use with any particular restriction device.

[0043] FIGS. 1A-1B illustrate one embodiment of an implantable restriction system 100. As shown, the implantable restriction system 100 generally includes a restriction device, e.g., an adjustable gastric band 120, that is configured to be positioned around the upper portion of a patient's stomach 140 to receive fluid and to form a restriction in a pathway corresponding to an amount of fluid contained therein. The restriction system 100 also includes a pressure control mechanism 130 and a fluid flow control mechanism 160 fluidly coupled, e.g., via a catheter 150 (which can be formed from one or more components), between the band 120 and the pressure control mechanism 130. The pressure control mechanism 130 is configured to control fluid introduction into and fluid removal from one or more elements included in the restriction system 100 to thereby adjust the size of the band 120 and thus the pressure applied to the stomach 140. The flow control mechanism 160 is configured to regulate a flow rate of fluid between the pressure control mechanism 130 and the band 120, thereby regulating a rate of pressure change. Although the flow control mechanism 160 can be disposed anywhere to control a rate of fluid delivery to and from the band 120, in the illustrated embodiment the catheter 150 includes a first portion that is coupled between the band 120 and the flow control mechanism 160 and a second portion that is coupled between the flow control mechanism 160 and the pressure control mechanism 130. Various configurations are possible, including configurations where one or more additional elements are fluidly coupled between any of the band 120, the pressure control mechanism 130, and the flow control mechanism 160, and any known restriction system or device can be used with the present invention.

[0044] FIG. 2A shows the gastric band 120 in more detail. While the gastric band 120 can have a variety of configurations, and various gastric bands known in the art can be used with the present invention, in the illustrated embodiment the gastric band 120 has a generally elongate shape with a support structure 122 having first and second opposite ends 120a, 120b that can be formed in a loop such that the ends are secured to each other. Various mating techniques can be used to secure the ends 120a, 120b to one another. In the illustrated embodiment, the ends 120a, 120b are in the form of straps that mate together, with one laying on top of the other. A support structure can be included at one end of the gastric band 120, and it can have an opening through which the other end of the gastric band 120 can feed through to secure the ends to one another. The gastric band 120 can also include a variable volume member, such as an inflatable balloon 124, that is disposed or formed on an internal side of the support structure 122 and that is configured to be positioned adjacent to tissue. The balloon 124 can expand or contract against the outer wall of the stomach to form an adjustable stoma for controllably restricting food intake into the stomach. The balloon 124 can receive fluid to expand and release fluid to contract. An amount of fluid within the balloon can correspond to an amount of restriction created by the band 120. Thus, adjustment of fluid in the band 120 can be used to control the amount of restriction formed by the band 120.

[0045] A person skilled in the art will appreciate that the gastric band 120 can have a variety of other configurations. Moreover, the various methods and devices disclosed herein have equal applicability to other types of implantable bands. For example, bands are used for the treatment of fecal incontinence, as described in U.S. Pat. No. 6,461,292 which is hereby incorporated by reference in its entirety. Bands can also be used to treat urinary incontinence, as described in U.S. Publication No. 2003/0105385 which is hereby incorporated by reference in its entirety. Bands can also be used to treat heartburn and/or acid reflux, as disclosed in U.S. Pat. No. 6,470,892 which is hereby incorporated by reference in its entirety. Bands can also be used to treat impotence, as described in U.S. Publication No. 2003/0114729 which is hereby incorporated by reference in its entirety.

[0046] FIG. 2B shows the adjustable gastric band 120 applied about the gastro-esophageal junction of a patient. As shown, the band 120 at least substantially encloses the upper portion of the stomach 140 near the junction with the patient's esophagus 142. After the band 120 is implanted, preferably in the deflated configuration wherein the band 120 contains little or no fluid, the band 120 can be inflated, e.g., using saline, to decrease the size of the stoma opening.

A person skilled in the art will appreciate that various techniques, including those described below, can be used to adjust the amount of restriction formed by the band 120.

[0047] The restriction system 100 can also optionally

include one or more sensors for sensing one or more parameters related to the system 100, such as pressure of the fluid within the closed fluid circuit of the system 100. While Dlugos discloses a pressure reading device, the sensor could be any sensing device for sensing various parameters of the system 100 or external to the system 100. The sensing device can also have various configurations, and it can be coupled to or positioned anywhere in the restriction system 100. In addition to sensing the pressure of fluid in the closed system, a pressure of fluid within the esophagus 142, the stomach 140, or other body lumen can also be sensed using a sensor, such as an endoscopic manometer. By way of non-limiting example, such fluid pressure measurements can be compared against the measured pressure of fluid within the system 100 before, during, and/or after adjustment of pressure within the system 100. Other suitable uses for measured pressure within the esophagus 142, the stomach 140, or other body lumen will be appreciated by those skilled in the art. The sensor can also be configured to measure various other physiological parameters, as may be desired.

[0048] FIG. 1B illustrates the restriction system 100 in more detail. As shown, the flow control mechanism 160 includes a flow control housing 170 and, optionally, an implantable fluid injection port 180 in fluid communication with the control housing 170 (e.g., via the catheter 150). The control housing 170 is also in fluid communication with the band 120 and with a fluid source 132 included in the pressure control mechanism 130 (e.g., via the catheter 150).

[0049] The pressure control mechanism 130 can have a variety of configurations. Generally, the pressure control mechanism 130 can be configured to regulate a pressure of fluid in the band 120 by controlling a flow of fluid between the band 120 and the fluid source 132. The pressure control mechanism 130 can include the fluid source 132 as illustrated in FIG. 1B, but the fluid source 132 can be a separate element included in the system 100 outside the pressure control mechanism 130. One exemplary embodiment of the pressure control mechanism 130 includes a fluid logic system configured to regulate a pressure of fluid in the band 120 in response to a fluid pressure acting thereon, such as a fluid logic system disclosed in more detail in commonly-owned U.S. Application No. 11/965,334 entitled "Fluid Logic For Regulating Restriction Devices," filed on December 27, 2007, which is hereby incorporated by reference in its entirety. Another exemplary embodiment of the pressure control mechanism 130 includes a transient pressure control mechanism configured to controllably release fluid from a fluid source (e.g., the fluid source 132) into the band 120 to help maintain a desirable pressure of fluid in the band 120, such as a transient pressure control mechanism disclosed in more detail in commonly-owned U.S. Application No. 11/965,331 entitled "Controlling Pressure In Adjustable Restriction Devices," filed on December 27, 2007, which is hereby incorporated by reference in its entirety. Still another embodiment of the pressure control mechanism 130 includes a substantially constant force mechanism configured to maintain a substantially constant pressure of fluid in the band 120 where an amount of fluid in the band 120 can correspond to an amount of restriction applied by the band 120, such as a substantially constant force mechanism disclosed in more detail in commonly-owned U.S. Application No. 11/965,322 entitled "Constant Force Mechanisms For Regulating Restriction Devices," filed on December 27, 2007, which is hereby incorporated by reference in its entirety. A person skilled in the art will appreciate that other pressure control mechanisms can be used as the pressure control mechanism 130 and that, as mentioned above, the fluid source 132 can be located external to the pressure control mechanism 130.

[0050] The fluid source 132 can also have various configurations, as discussed further below, and the restriction system 100 can include any number of fluid sources. For example, the fluid source 132 can include a pressured fluid reservoir in the form of a rigid or flexible housing coupled to the flow control mechanism 160 by a catheter (e.g., the catheter 150) or other connector. The pressured fluid reservoir can be a low pressure reservoir, a constant pressure reservoir, a high pressure reservoir, or various combinations thereof. The pressure can also change from low to high etc. Exemplary pressured fluid reservoirs are disclosed in more detail in previously mentioned U.S. Application No. 11/965,334 entitled "Fluid Logic For Regulating Restriction Devices," filed on December 27, 2007. As another example, the fluid source 132 can include the human body (e.g., the stomach, peritoneum, lung, saline generated through osmosis, intracellular fluids, blood, etc.). A catheter or other pathway can extend from the flow control mechanism 160 to a location in the body where it is desirable to obtain and/or release fluid. As yet another example, the fluid source 132 can include a pump system (e.g., a positive displacement pump and a centrifugal pump), such as those disclosed in more detail in previously mentioned U.S. Application No. 11/965,331 entitled "Controlling Pressure In Adjustable Restriction Devices," filed on December 27, 2007. As still another example, the fluid source 132 can include a constant force mechanism, such as those disclosed in more detail in previously mentioned U.S. Application No. 11/965,322 entitled "Constant Force Mechanisms For Regulating Restriction Devices," filed on December 27, 2007. The fluid source 132 can also or alternatively be included in the port 180 or in another, similar port. Additionally, if the fluid source 132 is not disposed in a port, it may or may not be in fluid communication with a port through a catheter or other connector to allow fluid to be introduced to and withdrawn from the fluid source 132.

[0051] In an exemplary embodiment, the fluid source 132 can include at least one pressured fluid reservoir contained within a housing. The pressure can be generated using various techniques known in the art, including

various techniques disclosed herein and discussed in more detail below. The maximum amount of fluid contained in the housing can be a sufficient volume of fluid to fill the band 120 and any connecting elements disposed between the band 120 and the fluid source 132, e.g., the catheter 150, the flow control mechanism 160, the pressure control mechanism 130, etc. The pressure P_1 of fluid within the fluid source 132 can be configured to allow the pressure P_2 of fluid within the band 120 to be at or substantially near its maximum pressure level when the band 120 is dormant (e.g., when the patient is not eating or drinking). The pressure P_1 of fluid within the fluid source 132 can also be configured such that the pressure control mechanism 130 can allow fluid to flow from the band 120 toward the fluid source 132 when the band 120 is not dormant (e.g., when the patient is eating or drinking) because the pressure P_2 in the band 120 would exceed the pressure P_1 in the fluid source 132. Similarly, when forces (e.g., peristaltic pulses from swallowing) stop acting on the band 120, the pressure P_2 in the band 120 can be lower than the pressure P_1 in the fluid source 132, and the pressure control mechanism 130 can allow fluid to flow from the fluid source 132 toward the band 120. The pressure P_1 in the fluid source 132 can be fixed or adjustable.

[0052] The fluid source 132 can have a variety of shapes, sizes, and configurations. FIGS. 3A-3D show various embodiments of a pressured fluid source 132. In the illustrated embodiment of FIG. 3A, the fluid source 300 generally includes a housing 302 (e.g., a rigid volume) having an internal cavity divided into two chambers with an inverse relationship, namely a biasing chamber 304 configured to have a biasing element disposed therein and a fluid chamber 306 configured to contain fluid. The housing 302 can have a variety of shapes and sizes, but in the illustrated embodiment the housing 302 is substantially cylindrical. The chambers 304, 306 can be separated by a movable translating surface 308. In the illustrated embodiment, forces acting on the translating surface 308 can include a force F_{fluid} in a direction toward the translating surface 308 and the housing's proximal end 309 caused by fluid in the fluid chamber 306 and a force F_{bias} in a direction toward the translating surface 308 and the housing's distal end 311 caused by a biasing mechanism 310 coupled to the translating surface 308. As shown, the biasing mechanism 310 is configured to bias the translating surface 308 toward the housing's distal end 311 and is thus configured to form a pressured fluid source 300. Generally, biasing the biasing mechanism 310 in the opposite direction, toward the housing's proximal end 309, can bias the fluid source 300 as a high pressure reservoir. When the pressure in the band 120 changes, the translating surface 308 can move in response as the force F_{fluid} in the fluid chamber 306 correspondingly changes. For example, when the pressure P_2 of fluid in the band 120 decreases, e.g., following eating, in response to any physiologic condition of the patient's anatomy, etc., the biasing force F_{bias} of the biasing mechanism 310 will be greater than a force applied to the fluid chamber 306 by the fluid in the band 120, and thus the translating surface 308 will move toward the housing's distal end 311 (e.g., increase the size of the biasing chamber 304 and decrease the size of the fluid chamber 306). This will allow fluid to flow from the fluid source 300 toward the band 120, thus increasing the pressure P_2 of fluid in the band 120. As the pressure P_2 increases, the force applied to the fluid chamber 306 by the fluid in the band 120 will overcome the biasing force F_{bias} to move the translating surface 308 back toward the closed position.

[0053] The biasing mechanism 310 can include any number of components configured to bias the translating surface 308, but in the illustrated embodiment the biasing mechanism 310 is a spring coupled to an inside surface of the housing 302 at one end of the spring and to the translating surface 308 at a second end of the spring. The translating surface 308 can have various configurations that allow the force F_{fluid} created by the fluid within the fluid chamber 306 to be transferred to the biasing mechanism 310. Additionally, the biasing mechanism 310 can be removable and/or adjustable to change the amount of force F_{bias} acting on the fluid. When the biasing mechanism 310 is a spring, the pressure limit of the fluid source 132 can be changed by changing the type of spring that is used, which can at least change the spring constant, and/or by changing the length of the spring that is used. FIG. 3B illustrates another embodiment of a fluid source 312 where instead of the biasing mechanism in the biasing chamber 304 being a spring, the biasing mechanism includes a fluid 314 in thermodynamic saturation.

[0054] The fluid chamber 306 can include any number of components configured to contain a fluid and bias the translating surface 308. In the embodiments shown in FIGS. 3A and 3B, fluid is freely disposed within the fluid chamber 306 (e.g., contained within inner surfaces of the housing 302). In another embodiment shown in FIG. 3C, a fluid source 320 is similar to the fluid source 300 of FIG. 3A, but the fluid source 320 of FIG. 3C includes a housing 322 having a single-chambered internal cavity 324 (and thus no translating surface separating chambers). The internal cavity 324 includes an expandable bladder, e.g., a bellows 326, and a biasing mechanism 328 disposed therein. The bellows 326 is configured to contain fluid and to be in fluid communication with other elements included in the restriction system 100 (e.g., the flow control mechanism 160, the band 120, etc.). The biasing mechanism 328 is a spring in this embodiment coupled to an inside surface of the housing 322 at one end of the spring and to an outside surface of the bellows 326 at a second end of the spring. FIG. 3D illustrates another embodiment of a fluid source 330 that, similar to the fluid source 320 of FIG. 3C, includes the housing 322 having the single-chambered internal cavity 324 with an expandable bladder, e.g., a bellows 336, disposed therein. Similar to the fluid source 312 of FIG. 3B, the fluid source 330 also

includes a fluid 338 in thermodynamic solution disposed within the housing 322 that acts as a biasing mechanism.

[0055] The flow control mechanism 160 of FIG. 1B can also have a variety of configurations. Generally, the control housing 170 includes a fluid communication member (e.g., a flexible tube) having a fluid pathway with a geometry that defines the flow rate of fluid through the control housing 170 and hence a flow rate between the band 120 and the fluid source 132. The geometry of the control housing's fluid pathway can be adjusted between a plurality of fixed positions, as discussed further below, thereby allowing for fixed but adjustable flow rates between the band 120 and the fluid source 132.

[0056] The flow control mechanism 160 (e.g., the control housing 170 and optionally the port 180) can have any configuration, size, and shape and can be made from any type of and any combination of materials, preferably biocompatible materials appropriate for use in a body, such as a polymer, a biocompatible metal (e.g., stainless steel and titanium), and other similar types of materials. The control housing 170 can be rigid or flexible and can be made from any combination of rigid and flexible materials, but, as discussed further below, the control housing 170 preferably has rigid top and bottom surfaces and a rigid perimeter wall, while the fluid communication member disposed within the control housing 170 is preferably flexible. The control housing 170 can have any shape. The control housing 170 can further include two or more catheter tube connection members in fluid communication with various elements included in the system 100 (e.g., the band 120, the pressure control mechanism 130, and the port 180) and configured to couple to a catheter (e.g., the catheter 150) or other connector.

[0057] The control housing 170 can optionally be coupled with a regulation mechanism, e.g., the port 180, that can be used to adjust the diameter of the fluid communication member within the control housing 170, as described further below. The control housing 170 and the port 180 are separate elements in fluid communication via the catheter 150, but in some embodiments, the control housing 170 and the port 180 can be included in a single housing. The port 180 can be configured to allow fluid to be introduced into and removed from one or more elements included in the restriction system 100, which in this example includes the control housing 170. The port 180 can thus be implanted at a location within the body that is accessible through the tissue. Typically, injection ports are positioned in the lateral subcostal region of the patient's abdomen under the skin and layers of fatty tissue. Surgeons also typically implant injection ports on the sternum of the patient. Generally, as fluid is introduced and removed through the port 180, fluid can be, respectively, introduced into and removed from the control housing 170, thereby adjusting the diameter of the fluid communication member within the control housing 170.

[0058] The port 180 can also have a variety of configurations, and it can optionally be provided in the system 100 to allow fluid or other materials to be introduced into various components of the system 100, such as the band 120, the flow control mechanism 160, and/or one or more fluid sources. In one embodiment shown in FIG. 4, the port 180 has a generally cylindrical housing with a distal or bottom surface and a perimeter wall extending proximally from the bottom surface and defining a proximal opening 182. The proximal opening 182 can include a needle-penetrable septum 184 extending there across and providing access to a fluid source or reservoir (not visible in FIG. 4) formed within the port's housing. The septum 184 is preferably placed in a proximal enough position such that the depth of the reservoir is sufficient enough to expose the open tip of a needle, such as a Huber needle, so that fluid transfer can take place. The septum 184 is preferably arranged so that it will self seal after being punctured by a needle and the needle is withdrawn. As further shown in FIG. 4, the port 180 can further include a catheter tube connection member 186 in fluid communication with the reservoir and configured to couple to a catheter (e.g., the catheter 150). A person skilled in the art will appreciate that the port's housing can be made from any number of materials, preferably biocompatible materials such as stainless steel, titanium, or polymeric materials, and the septum 184 can likewise be made from any number of materials, preferably biocompatible materials, including silicone.

[0059] As indicated above, the control housing 170 can have a variety of configurations, but FIG. 5 illustrates one exemplary embodiment of a flow control housing 170 having a body 172 with an internal cavity 178 having a fluid conduit 174 disposed therein. The illustrated fluid conduit 174 is in the form of an elongate tubular body having an inner pathway 176 extending longitudinally therethrough through which fluid can flow, but the fluid conduit 174 can have any configuration. Furthermore, the fluid conduit 174 can have any size and shape and can be made of any (preferably biocompatible) material (s), but it is preferably made from a flexible material to allow for adjustment of its geometry, such as its size, e.g., volume or diameter, and/or shape.

[0060] Generally, the fluid conduit 174 is configured to be in fluid communication with the band 120 and the fluid source 132 and to have a diameter D adjustable between two or more fixed positions. The diameter D in this embodiment defines an inner diameter of the fluid conduit 174, as illustrated in FIG. 6. The cross-section of the fluid conduit 174 is shown as substantially circular, but the fluid conduit 174 can have any cross-sectional shape, e.g., elliptical, rectangular, square, "D"-shaped, etc. The shape of the fluid conduit 174 determines the rate of fluid flow through the control housing 170, with a larger diameter D corresponding to faster flow rates (e.g., a higher fluid volume flow per second) and a smaller diameter D corresponding to slower flow rates (e.g., a lower fluid volume flow per second). In other words, adjusting the diameter D of the fluid conduit 174 can increase or decrease the size (e.g., volume) of the inner pathway 176

and hence increase or decrease a volume of fluid that can flow through the control housing 170 in a period of time. The flow rate (Q) through the fluid conduit 174 can be generally expressed as follows, where L equals the fluid conduit's longitudinal length, P_1 equals the pressure of fluid in the fluid source 132, and P_2 equals the pressure of fluid in the band 120:

$$Q \propto \frac{D}{L}(P_1 - P_2)$$

[0061] The diameter D can vary along the length L of the fluid conduit 174, as discussed further below, but as illustrated in FIG. 5, the fluid conduit 174 is in an equilibrium position where the diameter D is substantially constant along the fluid conduit's length L. In other words, in the equilibrium position, the diameter D of the fluid conduit 174 substantially equals the diameter D_C of the catheter 150 coupling the flow control mechanism 160 with the band 120 and with the fluid source 132 such that, in use, the flow control mechanism 160 effectively acts as part of the catheter 150 and does not substantially increase or decrease a rate of fluid flow through the control housing 170 as compared to a rate of fluid flow through the catheter 150 coupling the flow control mechanism 160 with the band 120 and with the fluid source 132. In this case, the catheter's diameter D_C is the catheter's inner diameter to appropriately correspond to the fluid conduit's diameter D.

[0062] The fluid conduit's diameter D can be adjusted in a variety of ways, but in certain exemplary embodiments, the size of the diameter D can be adjusted by introducing fluid into and removing fluid from the internal cavity 178 of the body 172. In other words, the fluid conduit 174 disposed within the internal cavity 178 can be allowed more or less expansion space within the internal cavity 178 depending on an amount of fluid disposed within the internal cavity 178 (external to the fluid conduit 174). Whether the body 172 is made from a rigid or a flexible material, the internal cavity 178 can have an internal area that can hold a finite amount of fluid (e.g., air, water, saline, etc.). When fluid is added to the internal cavity 178, the fluid conduit 174 can be constricted (e.g., the diameter D can decrease to decrease the volume of the inner pathway 176) to accommodate the additional fluid in the internal cavity 178. Correspondingly, when fluid is removed from the internal cavity 178, the fluid conduit can expand (e.g., the diameter D can increase to increase the volume of the inner pathway 176) given the newly freed space in the internal cavity 178. For example, the fluid cavity 178 can be in fluid communication with the port 180 (e.g., with a fluid reservoir included in the port 180). When an amount of fluid is introduced into or withdrawn from the flow control mechanism 160 through the port 180, a corresponding amount of fluid is introduced into or withdrawn from the internal cavity 178. Because the internal cavity 178 has a finite volume in which to accommodate fluid disposed therein and the fluid conduit 174 also disposed within the internal cavity 178, maintaining a constant amount of fluid in the internal cavity 178 allows the fluid conduit 174 to have a fixed position having a maximum diameter. The fluid conduit 174 can remain in the fixed position at least until (and if) the amount of fluid in the internal cavity 178 changes, when the fluid conduit 174 can change to another fixed position having a different maximum diameter D. The fluid conduit 174 can increase from any diameter to any increased diameter and decrease from any diameter to any decreased diameter.

[0063] As shown in one embodiment of an increased fluid conduit diameter in FIG. 7, fluid can be removed from the flow control mechanism 160 through the port 180 using a syringe 190, e.g., a Huber needle inserted through the port's septum 184, thereby reducing an amount of fluid in the control housing's internal cavity 178. With a reduction in the amount of fluid in the internal cavity 178, the fluid conduit 174 can increase from the equilibrium position having the diameter D to a second position having an increased diameter D_I, where D_I is greater than D. As shown in FIG. 7, the increased diameter D_I of the fluid conduit 174 is not constant along the length L of the fluid conduit 174 (although the increased diameter D_I could be constant along the length L in some embodiments). Rather, the diameter D of the fluid conduit 174 increases to the increased diameter D_I at least in a mid-portion of the fluid conduit 174 and remains substantially at the equilibrium diameter D at the fluid conduit's proximal and distal ends where the fluid conduit 174 couples with the body 172 so as to be in fluid communication with the catheter 150. The effect remains that decreasing an amount of fluid in the internal cavity 178 increases the fluid conduit's diameter and increases a volume of the inner pathway 176 through which fluid can flow between the band 120 and the fluid source 132.

[0064] Similarly, as shown in one embodiment of a decreased fluid conduit diameter in FIG. 8, fluid can be introduced to the flow control mechanism 160 through the port 180 using the syringe 190, thereby increasing an amount of fluid in the control housing's internal cavity 178. With an increase in the amount of fluid in the internal cavity 178, the fluid conduit 174 can reduce from the equilibrium position having the diameter D to a second position having a decreased diameter D_D, where D_D is less than D. As shown in FIG. 8, the decreased diameter D_D of the fluid conduit 174 is not constant along the length L of the fluid conduit 174 (although the decreased diameter D_D could be constant along the length L in some embodiments). Rather, the diameter D of the fluid conduit 174 decreases to a minimum diameter D_D at least in a mid-portion of the fluid conduit 174 and remains substantially at the equilibrium diameter D at the fluid conduit's proximal and distal ends. The effect remains that increasing an amount of fluid in the internal cavity 178 decreases

the fluid conduit's diameter and decreases a volume of the inner pathway 176 through which fluid can flow between the band 120 and the fluid source 132.

[0065] Because the body 172 is rigid in this embodiment, as shown in FIGS. 7 and 8, the body 172 does not change size or shape with removal of fluid from or introduction of fluid to the internal cavity 178, nor does the length L of the fluid conduit 174 change.

[0066] The diameter D of the fluid conduit 174 can vary even in a fixed position dependent on, for example, an amount of fluid flowing through the inner pathway 176. For example, the fluid conduit 174 can at least partially collapse to a smaller diameter at least in its mid-portion if little or no fluid is flowing through the flow control mechanism 160, e.g., because not enough fluid is flowing through the inner pathway 176 to allow the inner pathway 176 to expand to its maximum volume because substantially all fluid in the system's closed fluid circuit is in the band 120. However, the fluid conduit 174 still has a fixed position that cannot vary, e.g., the fluid conduit 174 cannot increase its volume beyond what is allowed in the internal cavity 178 by the amount of fluid disposed outside the fluid conduit 174 in the internal cavity 178.

[0067] While the syringe 190 is described as being manually operable to adjust an amount of fluid in the internal cavity 178 through the port 180, fluid need not actually transfer between the internal cavity 178 (or any part of the control housing 170) and the syringe 190. In other words, the amount of fluid in the internal cavity 178 can be adjusted by the mere shifting of fluid between the internal cavity 178 and the syringe 190 (e.g., by introducing fluid to or removing fluid from the fluid source or reservoir included in the port 180, which displaces fluid previously in the internal cavity 178 or displaces fluid into the internal cavity 178), as such shifting will cause similar shifting of fluid "upstream" of the internal cavity 178. It is not necessary for fluid being introduced into or removed from the internal cavity 178 through the port 180 to have actually come from or be withdrawn into the syringe 190 (or even from or into the port 180 because fluid can be displaced from within the catheter 150, or any other connectors, between the port 180 and the control housing 170). Furthermore, flow of any fluid discussed herein can include similar fluid shifting between two or more elements.

[0068] As discussed above, the flow control mechanism 160 can have various configurations, and the system 100 can include any number of fluid sources. For example, an amount of fluid in the control housing's internal cavity 178 can be adjusted directly through the control housing 170 rather than through the port 180 if, for example, the control housing 170 includes a septum (such as one similar to the septum 184) configured to allow fluid introduction to and fluid withdrawal from the internal cavity 178.

[0069] Any amount of fluid can be introduced into or withdrawn from the flow control mechanism 160 through the port 180 any number of times and at any frequency. The amount of fluid introduced into and/or withdrawn from the flow control mechanism 160, the number of times fluid is introduced into and/or withdrawn from the flow control mechanism 160, and the frequency of fluid adjustments can vary by patient and are preferably determined by the patient's physician (or other medical personnel) as part of a patient's treatment plan. Furthermore, the system 100 can be implanted in a patient with a particular amount of fluid in the flow control mechanism 160 (including no fluid in the flow control mechanism 160). Subsequent to implantation, the flow control mechanism 160 can be filled with an amount of fluid, such as by introducing fluid into the port 180 using the syringe 190.

[0070] While not shown, in another embodiment, the fluid conduit 174 can include a microcapillary, e.g., a capillary tube. The microcapillary can change its diameter D and its length L when fluid is added to or withdrawn from the internal cavity 178 (e.g., as described above using the port 180). In this embodiment, the body 172 is preferably flexible or at least partially flexible to allow the microcapillary to expand and contract in length. For example, as shown in one embodiment of a decreased fluid conduit diameter in FIG. 9, fluid can be introduced to the flow control mechanism 160 through the port 180 using the syringe 190, thereby increasing an amount of fluid in the control housing's internal cavity 178'. With an increase in the amount of fluid in the internal cavity 178', a fluid conduit 174' can reduce from the equilibrium position having the diameter D to a second position having a decreased diameter D_D constant along the length L_I of the microcapillary 174', where L_I is greater than L. Similarly, in another example shown in FIG. 10, fluid can be withdrawn from the flow control mechanism 160 through the port 180 using the syringe 190, thereby decreasing an amount of fluid in the control housing's internal cavity 178'. With a decrease in the amount of fluid in the internal cavity 178', the fluid conduit 174' can increase from the equilibrium position having the diameter D to a second position having an increased diameter D_I constant along the length L_D of the microcapillary 174', where L_D is less than L.

[0071] In some embodiments, the microcapillary 174' can have a spiraled A-A cross-section as shown in a variation of a microcapillary 174" in FIG. 11. The microcapillary 174" can have such a spiraled cross-section along its entire length L or along any one or more portions of its length L. Such a spiraled cross-section can allow the microcapillary 174" to increase and decrease its length L as fluid is, respectively, introduced into and withdrawn from the internal cavity 178'. In other words, the microcapillary 174" can act as an expansion cone. Preferably, the microcapillary's distal and proximal portions are each spiral-shaped such that the distal and proximal portions can expand and contract to change the length L of the microcapillary 174".

[0072] In another embodiment of a flow control mechanism 160', a diameter of the flow control mechanism

160' can be adjustably controlled through linear motion. As shown in one embodiment in FIG. 12, the flow control mechanism 160' includes a fluid pathway 200 in fluid communication with the band 120 and the fluid source 132. The fluid pathway 200 has a maximum diameter or thickness t_{max} along the fluid pathway's longitudinal length L2. The maximum thickness t_{max} of the fluid pathway 200 can be adjustable along at least a portion of its longitudinal length L2. In this illustrated example, a portion less than the fluid pathway's longitudinal length L2 has an adjustable diameter or thickness t. As the adjustable thickness t of the fluid pathway 200 changes, the flow rate through the flow control mechanism 160 changes and can generally be expressed as

$$Q \propto t(P_1 - P_2)$$

where the flow rate (Q) is maximized when the adjustable thickness t equals the maximum thickness t_{max}.

[0073] The adjustable thickness t can be adjusted between two or more fixed positions in a variety of ways. For example, a length l of an obstruction mechanism 202 extending into the fluid pathway 200 can define the adjustable thickness t of the fluid pathway 200. The length l can have any value (including zero, in which case the adjustable thickness t is at its maximum value t_{max} without any obstruction in the fluid pathway 200 being provided by the obstruction mechanism 202). Generally, the flow rate and the adjustable thickness t have a linear relationship such that increasing the length l decreases the diameter of and the flow rate through the fluid pathway 200, while decreasing the length l increases the diameter of and the flow rate through the fluid pathway 200.

[0074] As further show in FIG. 12, an adjustment mechanism 204 can be coupled to the obstruction mechanism 202, and it can be configured to change the length l of the obstruction mechanism 202 that extends into the fluid pathway 200. The adjustment mechanism 204 can have a variety of configurations, but in the illustrated embodiment of FIG. 12, the adjustment mechanism 204 is in the form of a fluid-filled bladder, e.g., a compressible bellows. The adjustment mechanism 204 can be fluidly coupled to the port 180 via the catheter 150 (or any other connector) to allow fluid to be introduced into and removed from the adjustment mechanism 204 via the port 180 (e.g., using the syringe 190) to assist in changing the length l of the obstruction mechanism 202 in the fluid pathway 200. By way of another non-limiting example, another adjustment mechanism 204 that can be used is a screw coupled to the obstruction mechanism 202. Rotation of the screw can be effective to increase and/or decrease a force applied by the screw to the obstruction mechanism 202, which in turn changes the length l of the obstruction mechanism 202 in the fluid pathway 200. By way of a further non-limiting example, another adjustment mechanism that can be used is a piston cylinder that can actuate the obstruction mechanism 202.

[0075] A person skilled in the art will also appreciate that the adjustment mechanism 204 can have particular characteristics that can be adjusted to change the length l of the obstruction mechanism 202 in the fluid pathway 200. For example, in embodiments where the adjustment mechanism 204 includes a spring, a spring constant or a length of the spring can be adjusted to change the length l of the obstruction mechanism 202 in the fluid pathway 200. The spring can be any flexible elastic object having any shape. For example, the spring can be a coil or helical spring having a cylindrical shape, although the spring can have other shapes, such as conical or dual conical, and it can have individual coils of any shape, such as elliptical or rectangular.

Other examples of the adjustment mechanism 204 include an elastic band, thread, or cord, a volute spring, and other similar types of flexible elastic objects. The spring can also have a variety of sizes, and, if more than one spring is used, different springs used for the adjustment mechanism 204 can have different sizes and shapes. Furthermore, if more than one spring or other biasing mechanism is used anywhere within the restriction system 100 (or other restriction system), each spring can be the same as or different from any other spring within the restriction system 100.

[0076] The obstruction mechanism 202 can have a variety of sizes, shapes, and configurations. Generally, a longitudinal axis A_O of the obstruction mechanism 202 extends substantially perpendicular to a longitudinal axis A_P of the fluid pathway 200 such that movement of the obstruction mechanism 202 substantially parallel to its axis A_O changes the length l of the obstruction mechanism 202 in the fluid pathway 200. In the embodiment shown in FIG. 12, the obstruction mechanism 202 is a substantially cylindrical, smooth, linear, rigid rod at least partially surrounded by a substantially fluid-impermeable bushing 206. However, the obstruction mechanism 202 can have any size, shape, and configuration that allows for its coupling with the adjustment mechanism 204. As the adjustment mechanism 204 expands (e.g., due to introduction of fluid into the adjustment mechanism 204 via introduction of fluid into the port 180), the obstruction mechanism 202 as a rigid member at least partially surrounded by the bushing 206 does not flex or bend but moves into the fluid pathway 200, thereby increasing the length l of the obstruction mechanism 202 in the fluid pathway 200. Similarly, as the adjustment mechanism 204 contracts (e.g., due to removal of fluid from the adjustment mechanism 204 via withdrawal of fluid from the port 180), the obstruction mechanism 202 also at least partially moves out of the fluid pathway 200, thereby decreasing the length l of the obstruction mechanism 202 in the fluid pathway 200.

[0077] Another embodiment of the obstruction mechanism is shown in FIG. 13. In this embodiment, the obstruction mechanism includes a threaded rod 208 at least

partially surrounded by a substantially fluid-impermeable bushing 210 that includes threads 212 configured to engage the threaded rod 208. An adjustment mechanism such as one described above (e.g., a bellows, a piston cylinder, etc.) can be used to rotationally actuate the threaded rod 208, thereby adjusting the thickness t and thus also the flow rate through the pathway 200.

[0078] In yet another embodiment of a flow control mechanism 160", a flow rate between the band 120 and the fluid source 132 can be controlled by regulating a flow of fluid through a porous membrane. As shown in FIG. 14, the flow control mechanism 160" includes a porous disc or a semi-permeable membrane 220 disposed in a membrane housing 222. The membrane housing 222 has proximal and distal ends 224, 226 fluidly coupled, respectively, to the band 120 and the fluid source 132. The membrane 220 is disposed between the proximal and distal ends 224, 226 in a mid-portion 228 of the membrane housing 222. The membrane 220 can be adapted to allow fluid to flow into and out of the membrane housing 222 while sealing any fluid contained in the membrane housing 222 from the outside environment. In one exemplary embodiment, the membrane 220 is made of cellulose acetate. The flow rate (Q) through the membrane housing 222 can be generally expressed as follows, where w represents an average width, diameter, or thickness of the membrane 220 and *d* represents a pore size of the membrane's pores through which fluid can flow:

$$Q \propto \frac{(P_1 - P_2)d}{w}$$

The pore size *d* and the average width *w* can each have any value. The pore size *d* is preferably substantially constant for a given membrane 220. The average width w can be adjusted, thereby adjusting the flow rate through the flow control mechanism 160".

[0079] The average width w of the membrane 220 can be adjusted in a variety of ways. One way that the average width w can be adjusted is by disposing the membrane housing 222 in a flow control housing (e.g., the flow control housing 170 discussed above) as illustrated in an embodiment in FIG. 15. An amount of fluid also disposed within the flow control housing 170 can be adjusted (e.g., by using the port 180 and the syringe 190 as discussed above), thereby allowing compression and expansion of the membrane housing 222 and thus also the width w of the membrane 220 disposed therein. Generally, more fluid in the flow control housing 170 corresponds to a smaller width w and a faster flow rate, while less fluid in the flow control housing 170 corresponds to a larger width w and a slower flow rate.

[0080] FIGS. 16-18 show one embodiment of the restriction system 100 in use. In the embodiment illustrated in FIGS. 16-18, the system 100 includes the pressured fluid source 300 of FIG. 3A and the flow control mechanism 160 of FIGS. 5-8 with the fluid conduit 174 having an adjustable diameter D. As shown, the fluid conduit's diameter 174 has the decreased diameter D_D of FIG. 8. In a dormant stage shown in FIG. 16, the band 120 substantially closes the stoma opening in the stomach 140, e.g., the stoma is in a dormant position because substantially no forces are acting on the stoma (aside from the force of the band 120 to substantially close the stoma). In other words, the patient is not eating, drinking, swallowing, vomiting, or otherwise voluntarily or involuntarily exerting a force on the esophagus 142, the stomach 140, and/or the band 120. In the dormant stage, fluid from the fluid source 300 substantially fills the band 120. In other words, the system 100 is in equilibrium. Additionally, fluid within the system 100 is stationary, e.g., fluid is not flowing through the flow control mechanism 160 between the band 120 and the fluid source 300.

[0081] When a force acts on the stoma (e.g., peristaltic waves from the patient ingesting food and swallowing), such as in a force stage shown in FIG. 17, the force can create a higher pressure P_2 in the band 120 than the pressure P_1 of the fluid source 300. Such a pressure differential ($P_2 > P_1$) can influence the pressure control mechanism 130 to allow fluid in the band 120 to flow from the band 120 toward the fluid source 300 via the flow control mechanism 160. As discussed above, the diameter D of the fluid conduit 174 can regulate the flow rate of fluid between the band 120 and the fluid source 300, thus regulating the rate at which the pressure changes. Because patient satiety is substantially determined by an amount of time it takes fluid in the band 120 to flow from the band 120 toward the fluid source 300, and hence an amount of time it takes for food to pass through the stoma (or be naturally digested before passing through the stoma), the decreased diameter D_D can allow for the patient to more quickly feel satiated and to feel satiated for a longer period of time because the flow rate through the control mechanism 160 is less than it would be through connective coupling of a substantially constant diameter between the band 120 and the fluid source 300. Similarly, if the diameter of the fluid conduit 174 was at the increased diameter D_1 of FIG. 7, the patient would feel satiated less quickly and for a shorter period of time because fluid would flow more quickly through the flow control mechanism 160 from the band 120 toward the fluid source 300. As such, a physician (or other authorized person) can adjust the diameter of the fluid conduit 174 any number of times over the course of the patient's treatment with the band 120 to, for example, provide for appropriate satiety of the patient. In other words, adjusting the diameter of the fluid conduit 174 can reduce or prevent rapid pressure changes in the band 120 that can reduce efficacy of the band 120 and affect a patient's eating patterns and/or overall weight control.

[0082] When the pressure control mechanism 130 has allowed enough fluid to flow from the band 120 toward the fluid source 300 via the fluid conduit 174, restriction

of the stomach 140 by the band 120 can be sufficiently low so as to allow passage of food through the stoma, as shown in a passage stage in FIG. 18. The patient's satiety level thereby decreases. When the force stops acting on the stoma (e.g., the patient stops eating), the pressure differential can reverse such that the pressure P_2 of fluid in the band 120 is less than the pressure P_1 of fluid in the fluid source 120, thereby allowing fluid to flow from the fluid source 300 toward the band 120.

[0083] In another embodiment, rather than altering the geometry of the flow control mechanism to adjust the rate of the fluid flow between a fluid source and a restriction device, a biasing mechanism can be used to define the flow rate through the flow control mechanism. FIG. 19A illustrates a flow control mechanism 410 coupled to a fluid source 412 for regulating fluid flow between the fluid source 412 and a restriction device 402. The flow control mechanism 410 includes a biasing mechanism, namely a fluid-filled housing 414, that controls a rate of movement of an actuator coupled to the fluid source 412. Movement of the actuator is effective to drive fluid between the fluid source 412 and the restriction device 402, and thus the rate of movement of the actuator corresponds to the rate of fluid flow between the fluid source 412 and the restriction device 402. The rate of movement can be adjusted, as discussed in more detail below. As will also be discussed in more detail, the flow control mechanism 410 can also include a pressure regulating mechanism for regulating a pressure of the restriction device 402.

[0084] As shown in FIG. 19A, the fluid source 412 is in the form of a bellows (although the fluid source can have a variety of configurations, as discussed above) that is in fluid communication with the restriction device 402 via a catheter 406. One end 400 of the bellows is fixed to a housing, while another end 404 is coupled to an actuator 416. The actuator 416 can have a variety of configurations, but as shown, the actuator 416 includes a rigid rod 428 coupled at one end to the fluid source 412 and at its other end to a porous member 418 (e.g., mesh, a porous membrane, a disc having a plurality of holes formed therein, or any other porous composition allowing fluid to flow therethrough) disposed within the fluid-filled housing 414. Movement of the porous member 418 within the fluid-filled housing 414 can control a rate of fluid flow between the restriction device 402 and the fluid source 412. The porous member 418 can move at a certain rate through the fluid-filled housing 414 depending on various factors, such as the shape and size of the rod 428 and the porous member 418 and the type of fluid 420 contained in the fluid-filled housing 414. The fluid 420 in the housing 414 can flow through the porous member 418 to regulate a rate of movement of the porous member 418 through the housing 414 to thereby also regulate a rate of movement of the rod 428 and hence the rate of fluid flow between the fluid source 412 and the restriction device 402. As the porous member 418 moves toward a distal end 422 of the fluid-filled housing 414, the fluid source 412 is expanded and hence fluid flows from the band 402 toward the fluid source 412 to decrease an amount of fluid in the restriction device 402. Similarly, as the porous member 418 moves toward a proximal end 424 of the fluid-filled housing 414, the fluid source 412 contracts to cause fluid to flow toward the restriction device 402 from the fluid source 412 to increase an amount of fluid in the restriction device 402.

[0085] A rate of movement of the porous member 418 through the fluid 420 can be controlled by the configuration of the porous member 418 (e.g., size and number of holes through which fluid can flow) and by the fluid's composition (e.g., a viscosity of the fluid). The fluid-filled housing 414 can optionally be in fluid communication with a port, as previously described, to allow the fluid 420 in the fluid-filled housing 414 to be replaced with fluid having a different viscosity to adjust the rate of the actuator's movement through the housing 414. Generally, the more viscous the fluid 420, the slower the rate at which the porous member 418 can move through the fluid 420.

[0086] The actuator 416 can also be coupled to a spring 426 that can regulate the fluid pressure in the restriction device 402. The spring 426 can provide a biasing force to the fluid source 412 to respond to pressure changes in the restriction device, as described in more detail in previously mentioned U.S. Application No. 11/965,322 entitled "Constant Force Mechanisms For Regulating Restriction Devices," filed on December 27, 2007. The spring's biasing force can be internally or externally adjusted, and the spring 428 can be replaceable.

[0087] In another embodiment, shown in FIG. 19B, the flow control mechanism 410 can include a second spring 434 coupled to a distal end 436 of the fluid-filled housing 414. When the porous member 418 disposed within the fluid-filled housing 414 is in a distal-most position adjacent to the housing's distal end 436, the spring 434 can allow the fluid source 412 to further expand, e.g., to continue to allow fluid to flow from the restriction device 402 toward the fluid source 412.

[0088] A person skilled in the art will appreciate that the present invention has application in conventional endoscopic and open surgical instrumentation as well application in robotic-assisted surgery.

[0089] The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disas-

sembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[0090] Preferably, the invention described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized.

In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

[0091] It is preferred that device is sterilized. This can be done by any number of ways known to those skilled in the art including beta or gamma radiation, ethylene oxide, steam.

[0092] One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

Claims

1. A restriction system for forming a restriction in a patient, comprising:

   an implantable restriction device configured to form a restriction in a pathway as a function of a volume of fluid contained in the restriction device; and

   an adjustable flow control mechanism in fluid communication with the restriction device and configured to define a rate of fluid flow to and from the restriction device.

2. The system of claim 1, wherein the adjustable flow control mechanism has an adjustable geometry that defines the rate of fluid flow to and from the restriction device.

3. The system of claim 2, wherein the flow control mechanism is configured to be adjustable between a plurality of fixed positions, and wherein increasing a volume of the geometry increases the rate of fluid flow and decreasing a volume of the geometry decreases the rate of fluid flow

4. The system of claim 2, wherein the flow control mechanism includes a flexible tube disposed in a housing and in fluid communication with the restriction device, wherein a geometry of the flexible tube is configured to be adjusted by modifying an amount of fluid within the housing to thereby adjust the rate of fluid flow.

5. The system of claim 4, wherein the housing is in fluid communication with an implantable port and the amount of fluid within the housing is configured to be modified through the port.

6. The system of claim 2, further comprising a fluid reservoir, wherein the geometry defines a rate of fluid flow between the restriction device and the fluid reservoir.

7. The system of claim 2, wherein the geometry comprises a diameter.

8. The system of claim 2, wherein the geometry of the flow control mechanism is configured to be adjusted through linear motion.

9. The system of claim 2, wherein the flow control mechanism includes a pathway in fluid communication with the restriction device, wherein a geometry of the pathway is configured to be adjusted by adjusting an amount of an obstruction mechanism within the pathway.

10. The system of claim 1, wherein the flow control mechanism includes a porous membrane.

11. The system of claim 1, wherein the flow control mechanism includes a porous member disposed within a fluid-filled housing, wherein fluid in the housing is configured to regulate a rate of movement of the porous member through the housing to thereby regulate the rate of fluid flow to and from the restriction device.

12. The system of claim 11, wherein the porous member is coupled to a fluid source in fluid communication with the restriction device such that movement of the porous member through the fluid-filled housing is effective to cause fluid to flow between the fluid source and the restriction device.

13. A restriction system, comprising:

   an implantable restriction device configured to contain a fluid and to form a restriction in a pathway corresponding to an amount of fluid in the restriction device;

   a fluid source in fluid communication with the restriction device for receiving fluid from the restriction device to decrease the restriction and

for delivering fluid to the restriction device to increase the restriction; and
an adjustable flow control mechanism disposed between the restriction device and the fluid source and configured to regulate a flow rate of fluid between the fluid source and the restriction device.

14. The system of claim 13, wherein the flow control mechanism has a diameter that is adjustable between at least two positions to regulate the flow rate of fluid.

15. A method of forming a restriction in a patient, comprising:

implanting a restriction device to form a restriction in a pathway that corresponds to a volume of fluid in the restriction device, and the restriction device receiving fluid from and delivering fluid to a fluid source at a flow rate defined by a geometry of a flow control mechanism in fluid communication with and disposed between the restriction device and the fluid source.

FIG. 1A

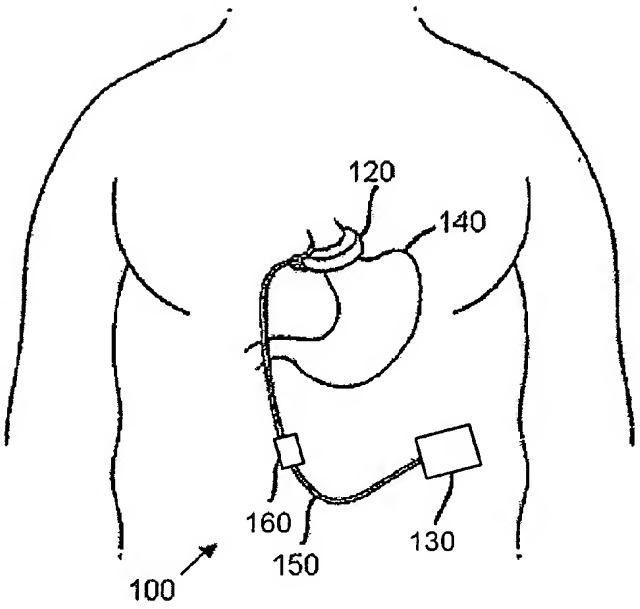


FIG. 1B

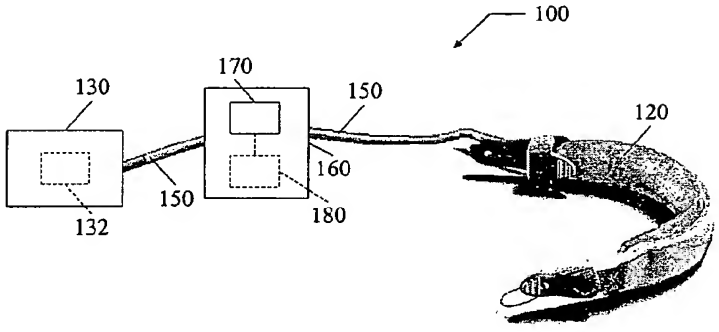


FIG. 2A

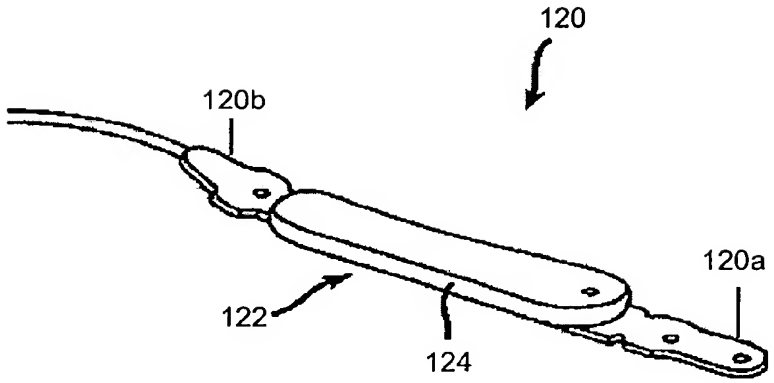


FIG. 2B

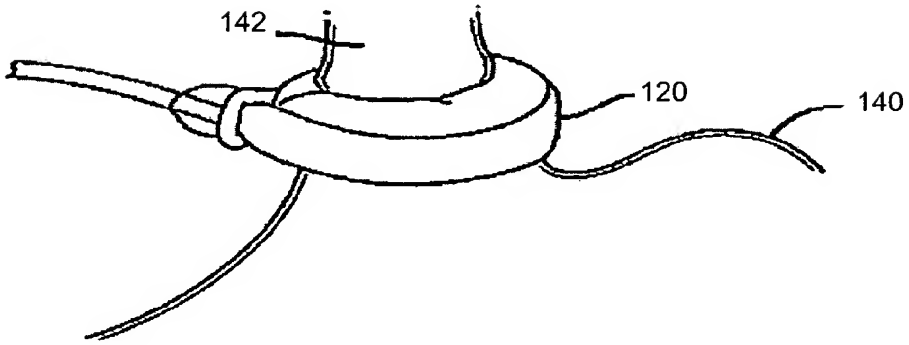


FIG. 3A

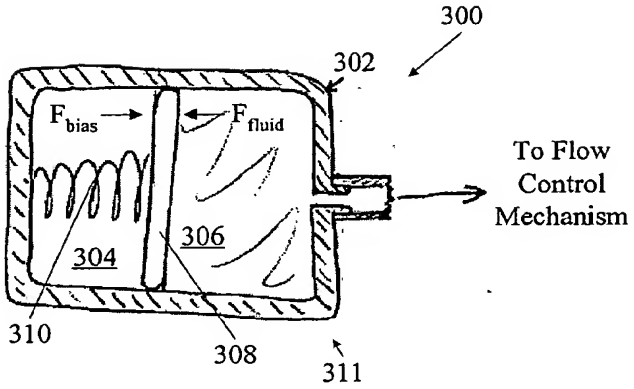


FIG. 3B

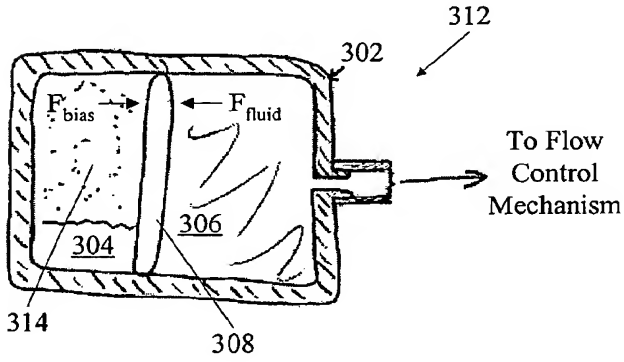


FIG. 3C

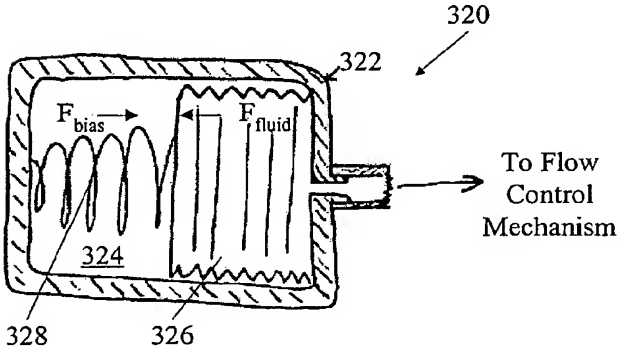


FIG. 3D

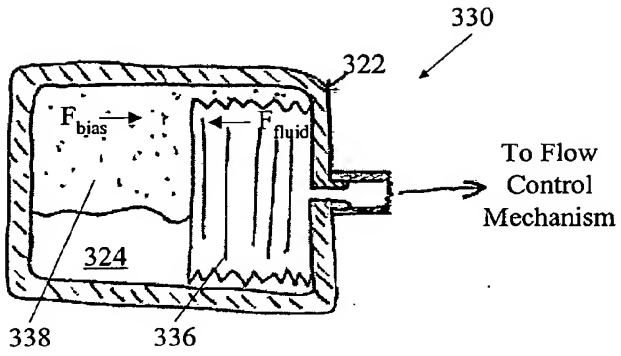

330
322
F_{bias}
F_{fluid}
To Flow Control Mechanism
324
338
336

FIG. 4

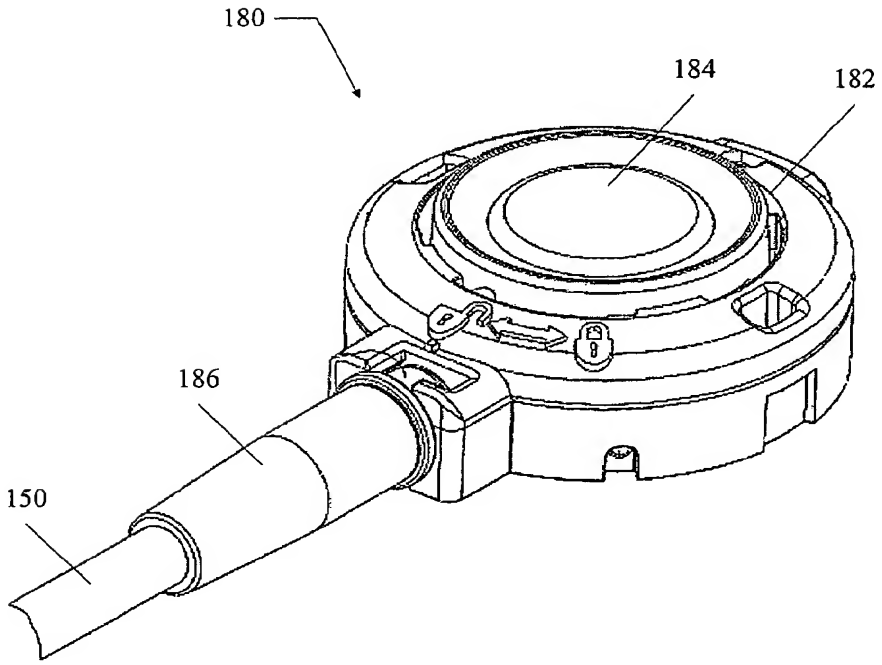

180
184
182
186
150

FIG. 5

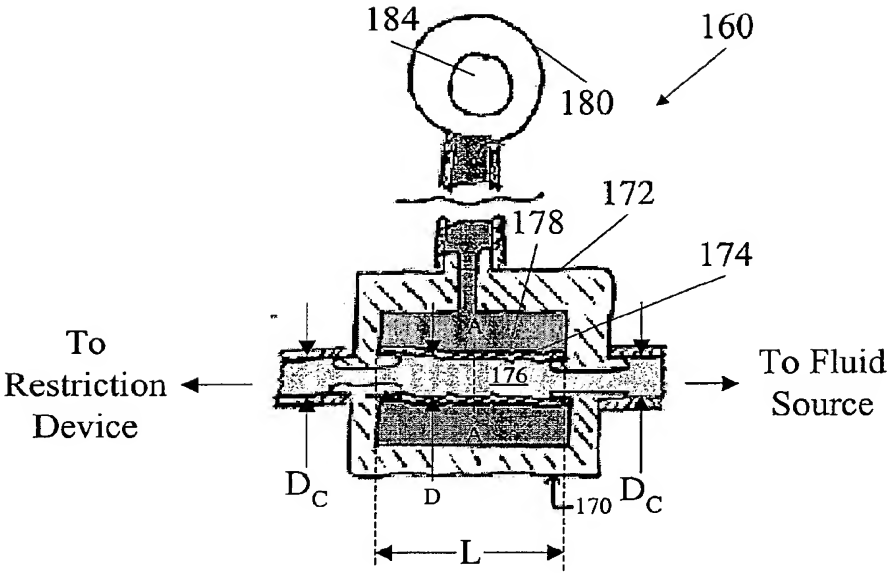

184
160
180
172
178
174
To
Restriction
Device
To Fluid
Source
176
D_C
D
170
D_C
L

FIG. 6

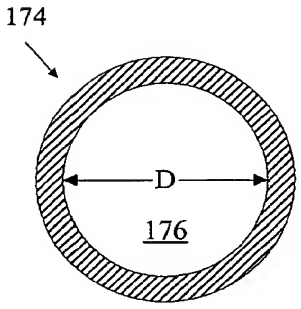

174
D
176

FIG. 7

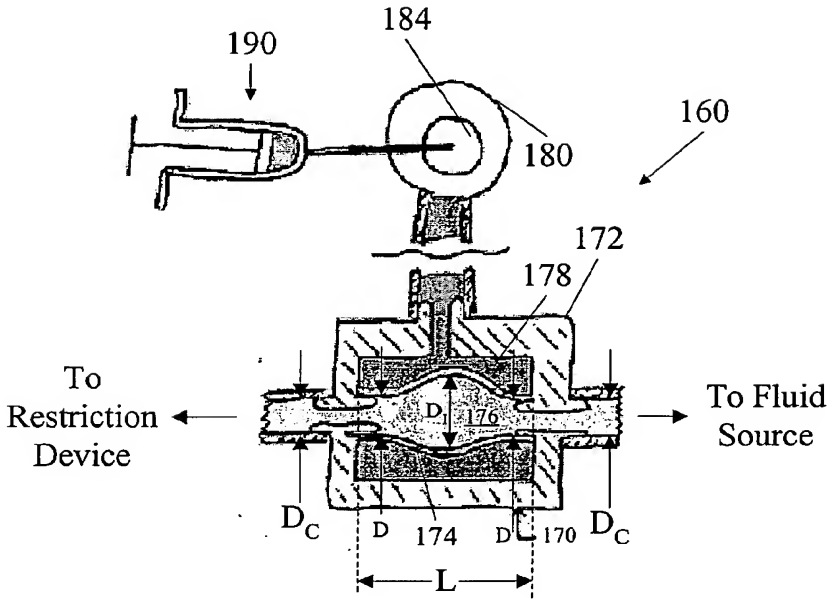

190
184
180
160
172
178
To
Restriction
Device
To Fluid
Source
D1
176
DC
D
174
D
170
DC
L

FIG. 8

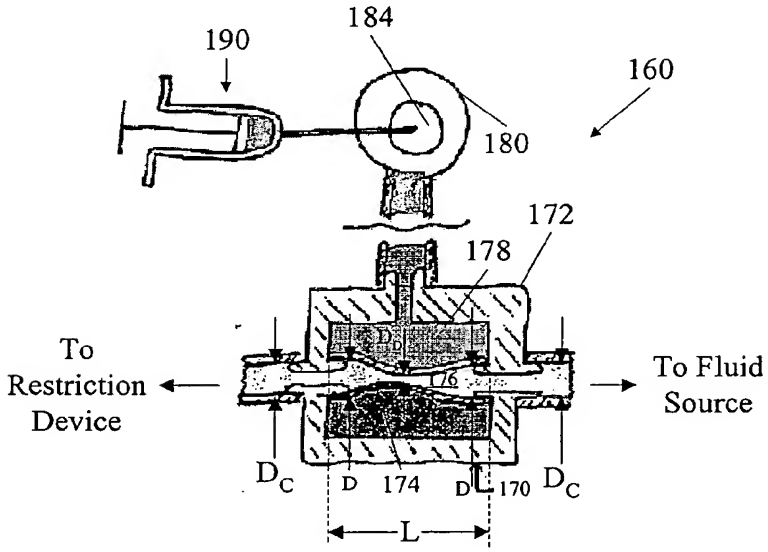

190
184
180
160
172
178
To
Restriction
Device
To Fluid
Source
D1
176
DC
D
174
D
170
DC
L

FIG. 9

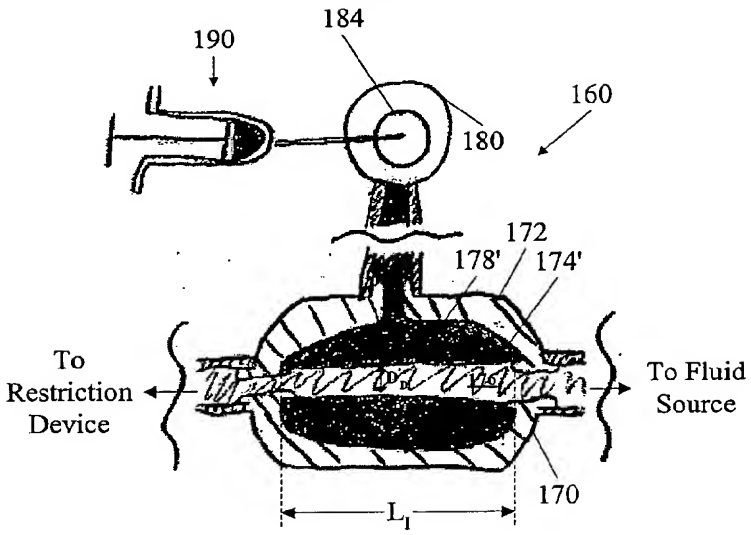

190
184
160
180
172
178'
174'
To
Restriction
Device
To Fluid
Source
170
L_I

FIG. 10

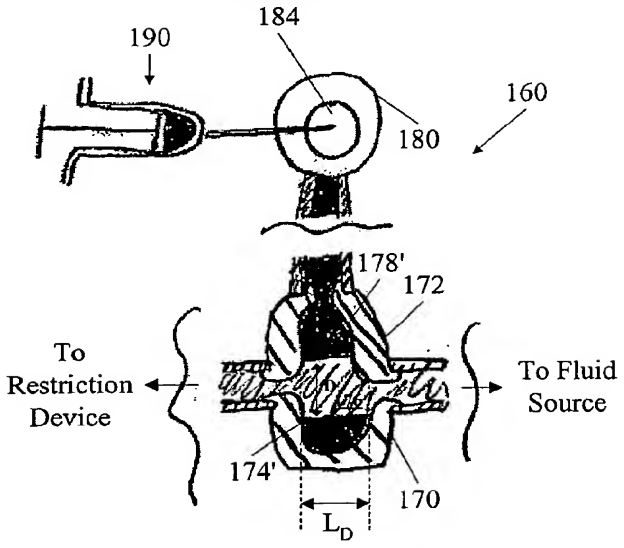

190
184
160
180
178'
172
To
Restriction
Device
To Fluid
Source
174'
170
L_D

FIG. 11

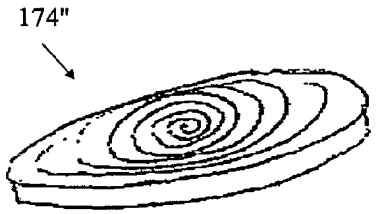

174"

FIG. 12

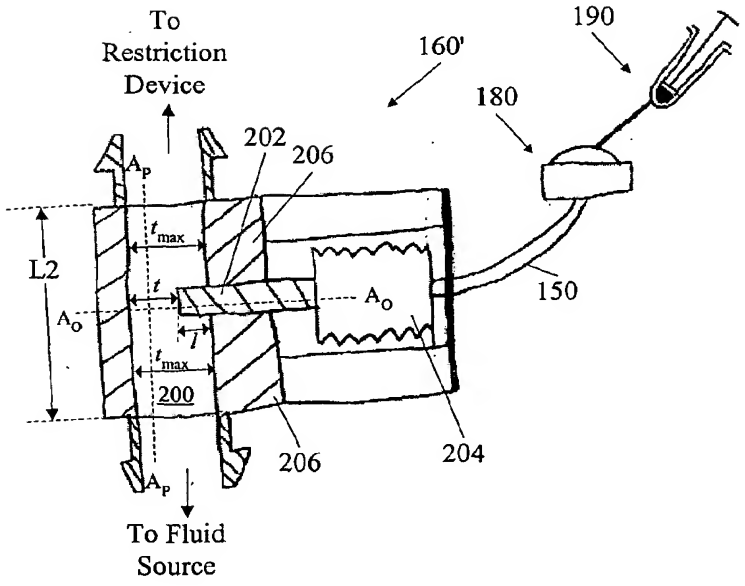

To
Restriction
Device
160'
190
180
202
206
A_P
t_{max}
L2
t
A_O
l
t_{max}
200
150
A_O
206
204
A_P
To Fluid
Source

FIG. 13

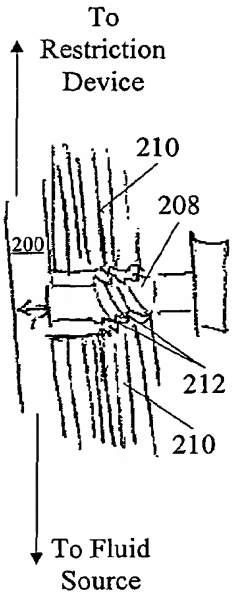


FIG. 14

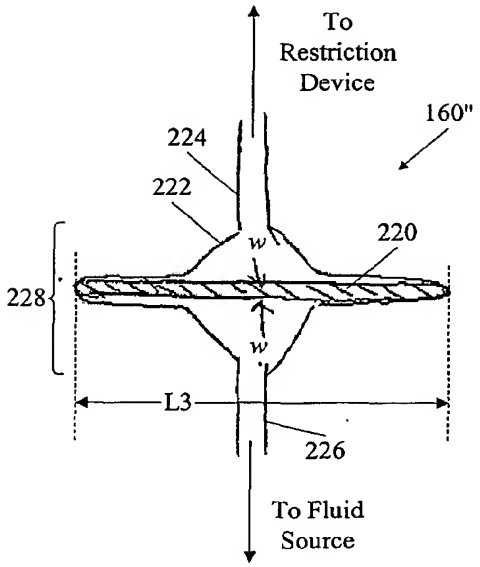


FIG. 15

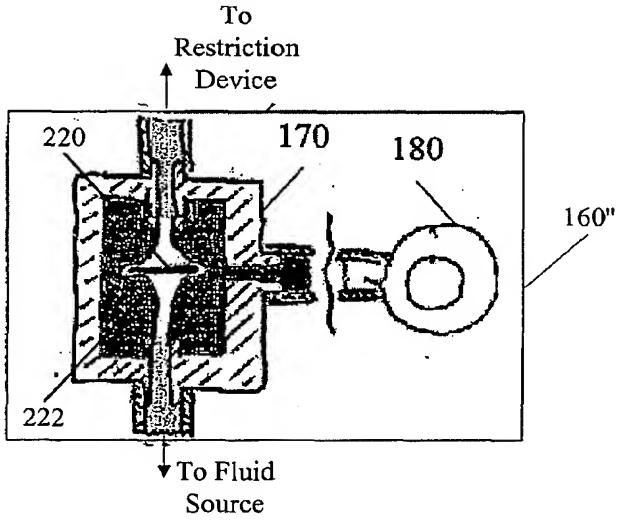


FIG. 16

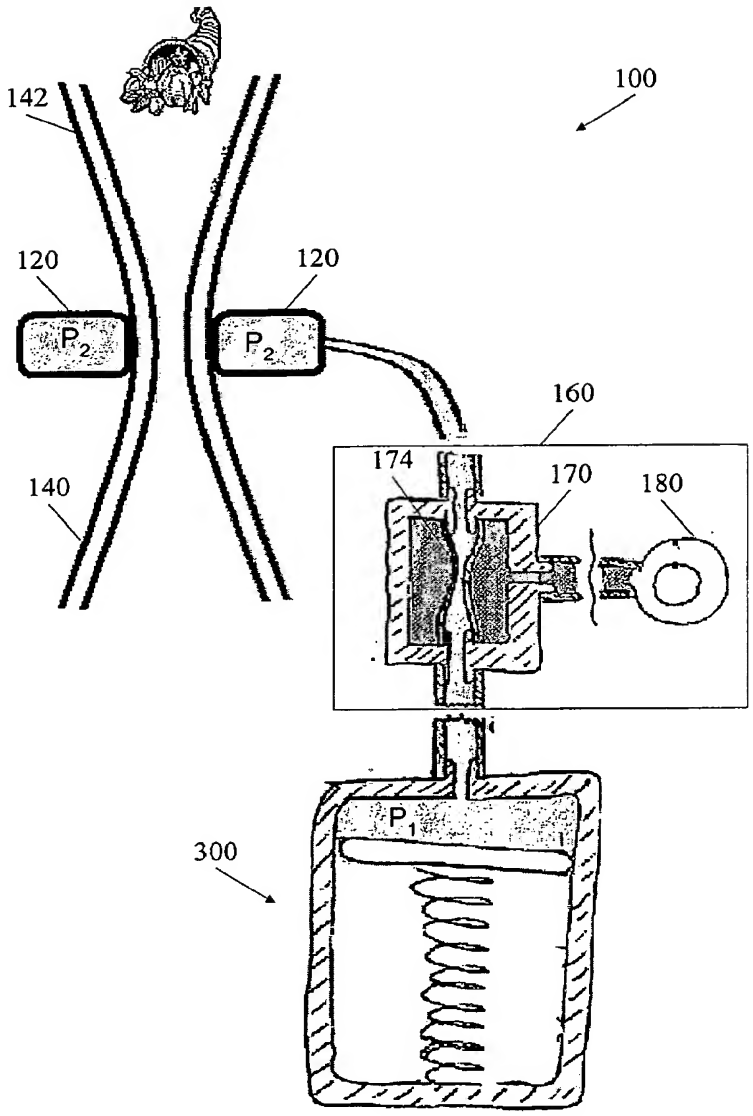


FIG. 17

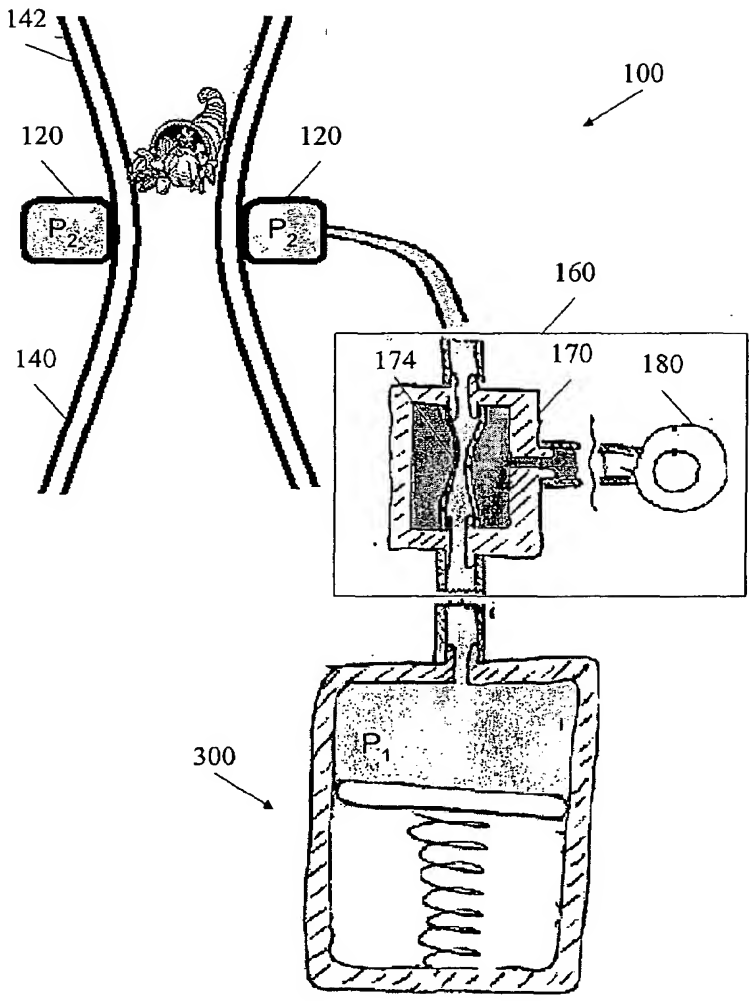


FIG. 18

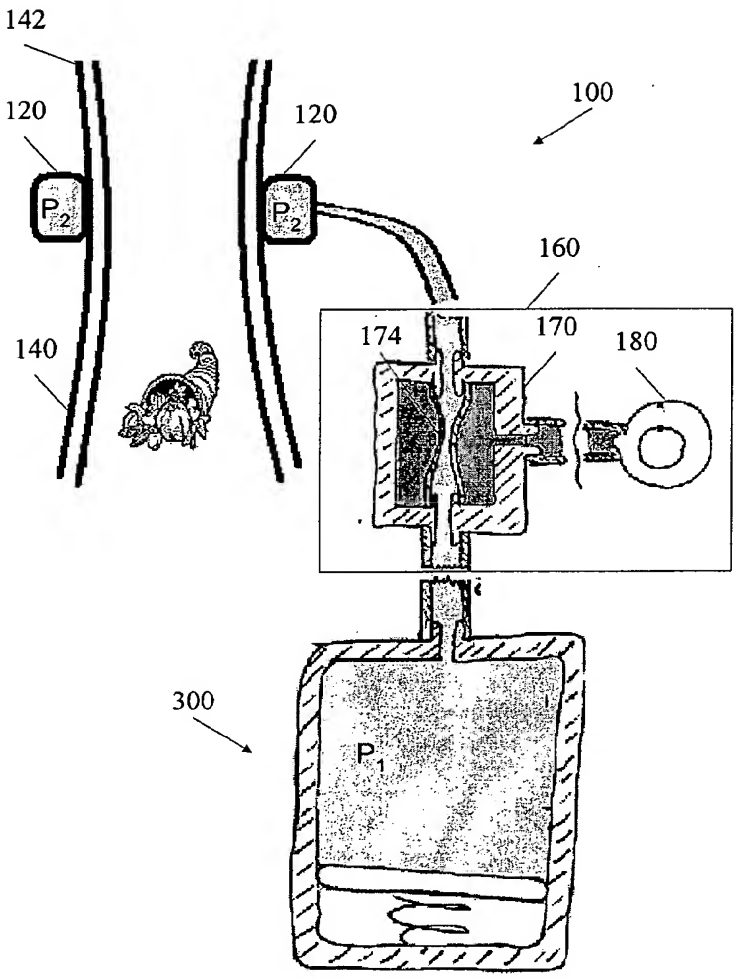


FIG. 19A

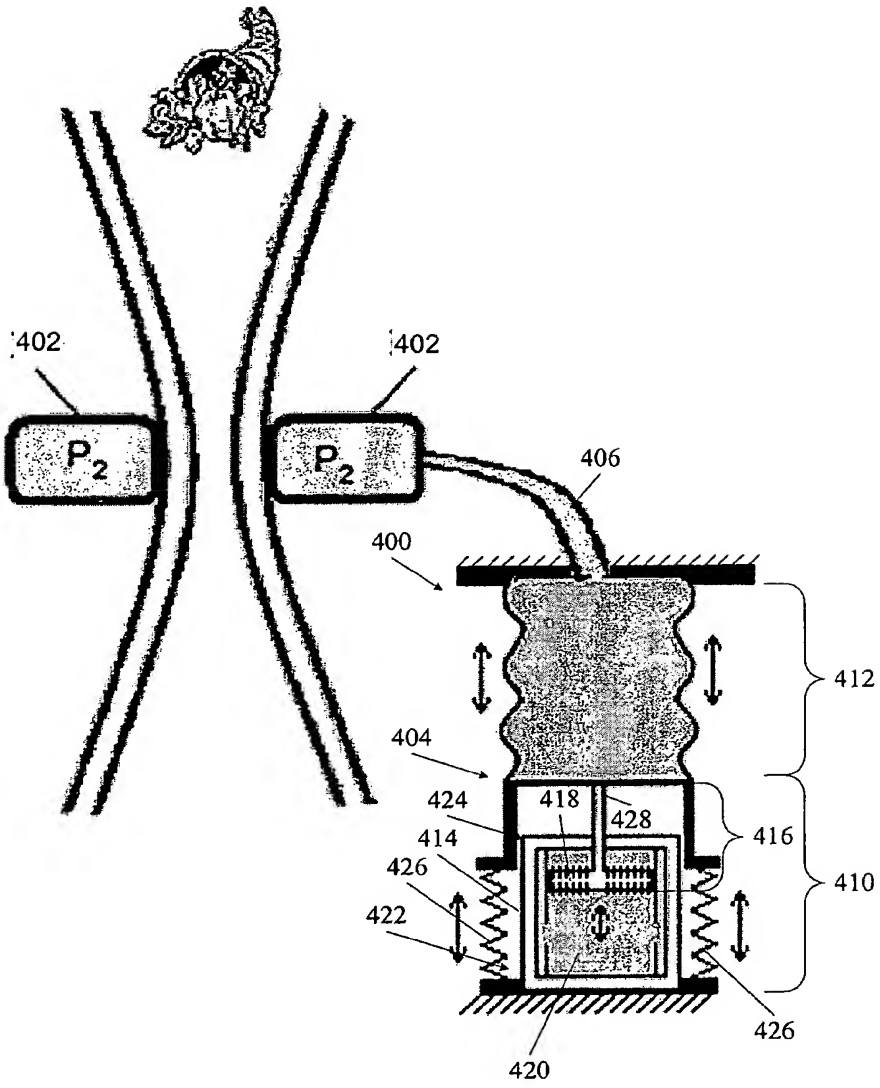
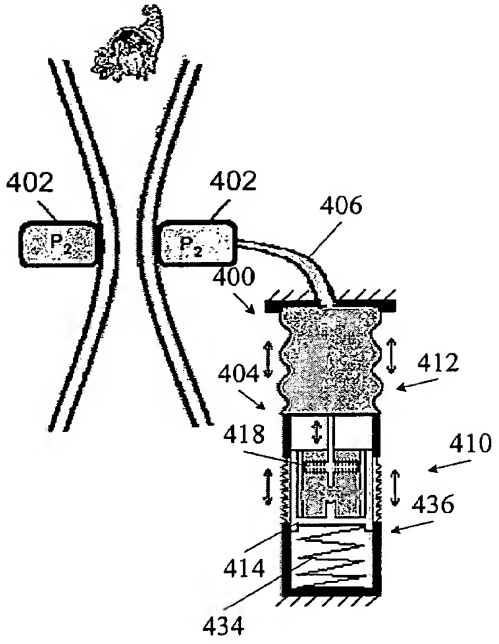

402
402
P_2
P_2
406
400
412
404
424
418
428
414
416
426
410
422
426
420

FIG. 19B



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PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 63 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

EP 09 25 0497

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X A	US 2007/156013 A1 (BIRK JANEL [US]) 5 July 2007 (2007-07-05) * abstract; figures * * paragraphs [0003], [0008], [0009], [0031] - [0040], [0058] - [0084], [0102] - [0122] *	1,13 2-12,14	INV. A61F5/00
X A	WO 00/09047 A (FORSELL PETER [CH]) 24 February 2000 (2000-02-24) * abstract; figures 11-14,29A-35 * * page 21, lines 11-32 * * page 23, line 30 - page 29, line 19 *	1,13 2-12,14	
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-/--

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :

Claims searched incompletely :

Claims not searched :

Reason for the limitation of the search:

see sheet C

Place of search	Date of completion of the search	Examiner
Munich	29 April 2009	Lager, Johan

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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1

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PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 09 25 0497

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (IPC)
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X A	WO 2006/108203 A (LECHNER WOLFGANG [AT]) 19 October 2006 (2006-10-19) * abstract; figures * * page 1, paragraph 1 * * page 3, paragraph 1 - page 5, paragraph 3 * -----	1 2-14	
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EPO FORM 1503 03.82 (P04C10)

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European Patent Office
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INCOMPLETE SEARCH
SHEET C

Application Number
EP 09 25 0497

Claim(s) not searched:
15

Reason for the limitation of the search (non-patentable invention(s)):

Article 53 (c) EPC - Method for treatment of the human or animal body by surgery

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 09 25 0497

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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29-04-2009

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